

§ 40.185

5(b)) on Copy 1 of the CCF, as appropriate, and by providing clarifying remarks using current HHS Mandatory Guidelines requirements.

(b) As the laboratory certifying scientist, enter your name, sign, and date the CCF.

[65 FR 79526, Dec. 19, 2000, as amended at 73 FR 35972, June 25, 2008]

§ 40.185 Through what methods and to whom must a laboratory report split specimen results?

(a) As the laboratory testing the split specimen, you must report laboratory results directly, and only, to the MRO at his or her place of business. You must not report results to or through the DER or another service agent (e.g., a C/TPA).

(b) You must fax, courier, mail, or electronically transmit a legible image or copy of the fully-completed Copy 1 of the CCF, which has been signed by the certifying scientist.

(c) You must transmit the laboratory result to the MRO immediately, preferably on the same day or next business day as the result is signed and released.

§ 40.187 What does the MRO do with split specimen laboratory results?

As the MRO, the split specimen laboratory results you receive will fall into five categories. You must take the following action, as appropriate, when a laboratory reports split specimen results to you.

(a) *Category 1:* The laboratory reconfirmed one or more of the primary specimen results. As the MRO, you must report to the DER and the employee the result(s) that was/were reconfirmed.

(1) In the case of a reconfirmed positive test(s) for drug(s) or drug metabolite(s), the positive is the final result.

(2) In the case of a reconfirmed adulterated or substituted result, the refusal to test is the final result.

(3) In the case of a combination positive and refusal to test results, the final result is both positive and refusal to test.

(b) *Category 2:* The laboratory failed to reconfirm all of the primary specimen results because, as appropriate, drug(s)/drug metabolite(s) were not de-

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tected; adulteration criteria were not met; and/or substitution criteria were not met. As the MRO, you must report to the DER and the employee that the test must be cancelled.

(1) As the MRO, you must inform ODAPC of the failure to reconfirm using the format in Appendix D to this part.

(2) In a case where the split failed to reconfirm because the substitution criteria were not met and the split specimen creatinine concentration was equal to or greater than 2mg/dL but less than or equal to 5mg/dL, as the MRO, you must, in addition to step (b)(1) of this paragraph, direct the DER to ensure the immediate collection of another specimen from the employee under direct observation, with no notice given to the employee of this collection requirement until immediately before the collection.

(3) In a case where the split failed to reconfirm and the primary specimen's result was also invalid, direct the DER to ensure the immediate collection of another specimen from the employee under direct observation, with no notice given to the employee of this collection requirement until immediately before the collection.

(c) *Category 3:* The laboratory failed to reconfirm all of the primary specimen results, and also reported that the split specimen was invalid, adulterated, and/or substituted.

(1) In the case where the laboratory failed to reconfirm all of the primary specimen results and the split was reported as invalid, as the MRO, you must:

(i) Report to the DER and the employee that the test must be cancelled and the reason for the cancellation.

(ii) Direct the DER to ensure the immediate collection of another specimen from the employee under direct observation, with no notice given to the employee of this collection requirement until immediately before the collection.

(iii) Inform ODAPC of the failure to reconfirm using the format in Appendix D to this part.

(2) In the case where the laboratory failed to reconfirm any of the primary

specimen results, and the split was reported as adulterated and/or substituted, as the MRO, you must:

(i) Contact the employee and inform the employee that the laboratory has determined that his or her split specimen is adulterated and/or substituted, as appropriate.

(ii) Follow the procedures of § 40.145 to determine if there is a legitimate medical explanation for the laboratory finding of adulteration and/or substitution, as appropriate.

(iii) If you determine that there is a legitimate medical explanation for the adulterated and/or substituted test result, report to the DER and the employee that the test must be cancelled; and inform ODAPC of the failure to reconfirm using the format in Appendix D to this part.

(iv) If you determine that there is not a legitimate medical explanation for the adulterated and/or substituted test result, you must take the following steps:

(A) Report the test to the DER and the employee as a verified refusal to test. Inform the employee that he or she has 72 hours to request a test of the primary specimen to determine if the adulterant found in the split specimen is also present in the primary specimen and/or to determine if the primary specimen meets appropriate substitution criteria.

(B) Except when the request is for a test of the primary specimen and is being made to the laboratory that tested the primary specimen, follow the procedures of §§ 40.153, 40.171, 40.173, 40.179, 40.181, and 40.185, as appropriate.

(C) As the laboratory that tests the primary specimen to reconfirm the presence of the adulterant found in the split specimen and/or to determine that the primary specimen meets appropriate substitution criteria, report your result to the MRO on a photocopy (faxed, mailed, scanned, couriered) of Copy 1 of the CCF.

(D) If the test of the primary specimen reconfirms the adulteration and/or substitution finding of the split specimen, as the MRO you must report the result as a refusal to test as provided in paragraph (a)(2) of this section.

(E) If the test of the primary specimen fails to reconfirm the adulteration

and/or substitution finding of the split specimen, as the MRO you must cancel the test, following procedures in paragraph (b) of this section.

(d) *Category 4:* The laboratory failed to reconfirm one or more but not all of the primary specimen results, and also reported that the split specimen was invalid, adulterated, and/or substituted. As the MRO, in the case where the laboratory reconfirmed one or more of the primary specimen result(s), you must follow procedures in paragraph (a) of this section and:

(1) Report that the split was also reported as being invalid, adulterated, and/or substituted (as appropriate).

(2) Inform the DER to take action only on the reconfirmed result(s).

(e) *Category 5:* The split specimen was not available for testing or there was no split laboratory available to test the specimen. As the MRO, you must:

(1) Report to the DER and the employee that the test must be cancelled and the reason for the cancellation;

(2) Direct the DER to ensure the immediate recollection of another specimen from the employee under direct observation, with no notice given to the employee of this collection requirement until immediately before the collection; and

(3) Notify ODAPC of the failure to reconfirm using the format in Appendix D to this part.

(f) For all split specimen results, as the MRO you must in Step 7 of Copy 2 of the CCF:

(1) Report split specimen test results by checking the "Reconfirmed" box and/or the "Failed to Reconfirm" box, or the "Test Cancelled" box, as appropriate.

(2) Enter your name, sign, and date.

(3) Send a legible copy of Copy 2 of the CCF (or a signed and dated letter, see § 40.163) to the employer and keep a copy for your records. Transmit the document as provided in § 40.167.

[73 FR 35973, June 25, 2008, as amended at 75 FR 59108, Sept. 27, 2010]

§ 40.189 Where is other information concerning split specimens found in this regulation?

You can find more information concerning split specimens in several sections of this part: